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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,425	03/15/2002	Hiroaki Shibasaki	1576.99	1761
24040	7590	11/19/2002	EXAMINER	
MASON & ASSOCIATES, PA 17757 US HWY 19 N. SUITE 500 CLEARWATER, FL 33764			MURPHY, JENNIFER C	
		ART UNIT	PAPER NUMBER	
		1626		

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

	Application No.	Applicant(s)
	10/088,425	SHIBASAKI ET AL.
Examiner	Art Unit	
Jennifer C. Murphy	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09/20/02.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,9-14 and 19-21 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5,8 and 15-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-21 are pending in this application.

Election/Restriction

In response to the restriction requirement mailed by the Office on 08/30/02, applicant has timely responded with the election of group I, claims 1-5, 8 and 15-18 drawn to methods of making and entered as paper #6. Claims 6, 7, 9-14 and 19-21 hereby stand withdrawn from further consideration, as they are drawn to non-elected subject matter.

Response to Arguments

In response to arguments set forth in paper #6, entered by the Office on 09/20/02, the examiner has taken the arguments fully into consideration. However, the restriction is believed, by the examiner, to be proper and stands as previously stated in paper #5. As applicant has stated, there is a close relationship between groups I-VI (see page 2 of paper #6). This relationship does not define a technical feature over the prior art, as it is in the form of substituted carboxamide derivatives. Take for example, groups I and II. Group I is drawn to making a compound of the general formula (I) wherein group II is drawn to making a compound of the general formula (II), a compound that appears to be similar in structure to the starting product of group I, not the end product. Again, take for example groups IV and V. Group IV is drawn to making a compound of general formula (V), a substituted cyano group whereas group V is drawn to the compounds of general formula (II); the method of making compound of formula (V) would require a different search than searching the compound of formula (II) alone.

The examiner directs applicants to 37 CFR 1.499, wherein it is stated the "basic principle" behind lack of unity among claims in an application filed during the national stage is that the "application should relate to only one invention." For reasons mentioned on record, the groups as listed by the examiner lack unity of invention and therefore, restriction is deemed proper.

Notice of Correction

The examiner apologizes for having caused applicant any unnecessary concern when the examiner failed to correctly acknowledge receipt, by the Office, the priority documents (total of three documents), entered as paper #2.

Claim Objections

Claims 15, 17 and 18 depend from both elected and non-elected subject matter and are also objected to. These objections may be overcome by placing the claims either in independent form or changing the dependency so as to depend from elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, in each of the four claims mentioned supra, the claim recites the definition of various substituents (for example, R1) for formulae (I) through (VI). However, the compounds of formulae (III) and (IV) do not fall within the elected subject matter, rendering the claims vague. These rejections may be overcome by, for example, deleting formula "(III)" and "(IV)" from the claims mentioned supra.

Furthermore, claims 15-18 recite the limitation "formula (III) and/or (IV)" when there is insufficient antecedent basis for this limitation in the claim (see arguments mentioned supra).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5 & 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Booth, et al. (*J Chem Soc Perkin Trans 1*, 1987).

The instant claims are directed to a process of preparing 4(5)-amino-5(4)-carboxamidazole derivatives by subjecting substituted amino-dicyanoformamidine derivatives to cyclization and hydrolysis in an aqueous basic solution.

1. Claim 1 recites a process to obtain the compound of formula (I) where R₁ is C₁-C₁₀ alkyl and R₂ is hydrogen, by cyclizing and hydrolyzing in an aqueous basic solution, the compound represented by formula (II), with the same R group substituents as mentioned supra. The Booth reference meets the instant limitations when it discloses a dicyanoformamidine compound of formula (6) subjected to hydrolysis and cyclization by the addition of NaOH and heat (see page 1522, reaction scheme labeled 'v' and page 1524, fourth paragraph down, left-hand column).

2. Claim 2 recites the same process as in claim 1 but further limits the claim by adjusting the pH (see page 27). The Booth reference meets the limitations when it discloses "...until pH 10-11 was reached." on page 1524, fourth paragraph down, left-hand column.

3. Claim 3 again recites the same process as in claim 1 but further limits it by giving the pH range of 9-13. The Booth reference meets the limitations when it discloses "...until pH 10-11 was reached." Again, see page 1524, fourth paragraph down, left-hand column.

4. Claim 5 recites the basic compound is "...sodium hydroxide" wherein the Booth reference meets this limitation when it discloses the use of sodium hydroxide as the aqueous basic solution (see page 1522, reaction scheme labeled 'v' and page 1524, fourth paragraph down, left-hand column).

5. Claim 8 recites the use of ethyl alcohol in the process wherein the Booth reference meets this limitation when it discloses the use of ethanol in the same process see page 1524, fourth paragraph down, left-hand column.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 & 15-18 are rejected under 35 U.S.C. 103(a) as being un-patentable over Booth, et al (*J Chem Soc Perkin Trans 1*, 1987).

Applicants instantly claim a process for preparing 4(5)-amino-5(4)-carboxamidazole derivatives by subjecting substituted amino-dicyanoformamidine derivatives to cyclization and hydrolysis in an aqueous basic solution.

Determination of the scope and content of the prior art (MPEP §2141.01)

The Booth reference teaches the preparation of 5-amino-1,2-dimethyl-1H-imidazole-4-carboxamide by subjecting substituted amino-dicyanoformamidine derivatives of formula (b) to cyclization and hydrolysis in an aqueous solution (see page 1524, 4th paragraph in left-hand column, where “aqueous NaOH was added....”), which meets the limitations of the instantly claimed process when, in the instant claims, R₁ and R₂ are –CH₃ (see line 5 of claim 1 on page 36; lines 1-2 in claim 2 on page 37; lines 1-2 on page 38 in claim 3; lines 2-3 on page 43 of claim 15; lines 3-4 on page 44 in claim 16; lines 3-4 on page 46 in claim 17; and lines 3-4 on page 46 in claim 18, all of which recite a “C₁-C₁₀ alkyl” either straight chain or branched, as well as when said substituents can be hydrogen (see lines 4-5 of claim 1 on page 36; line 2 of claim 2 on page 37; line 1 of claim 3, page 38; line 1 of page 43 of claim 15; line 2 of claim 17 on page 46). The limitations of the claims are also met when the instant claims recite “unsubstituted alkyl group of C1-C10 having straight or branched chains.”

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The Booth reference discloses end products, defined on page 1522 where R₁ is methyl (in reaction “v”), which generically read on similar compounds as those instantly claimed, where the N-methyl-2-amino-1,2-dicyanoformamidine compound (end-product) meets the limitations of the instantly claims when R₁ and R₂ are hydrogen and lower alkyl.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

However, it would have been prima facie obvious for one of ordinary skill in the art at the time of filing the invention to not only make and use additional compounds from under the prior art genus as generically taught by Booth, et al. wherein a C1-C10 alkyl, specifically, a methyl (as disclosed by the reference) is used with the expectation of obtaining compounds with similar or the same properties, absent any unexpected results, thereby motivating one of ordinary skill in the art, but also, to modify the process as taught by Booth, et al. Wherein applicants claim hydrogen as R1 and R2, and the Booth reference embodies only methyl, it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *In re Wood*, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and *In re Lohr*, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity. Similarly, wherein applicants would employ an ethyl group for R1 and/or R2, such a group would be an obvious homologue to the methyl employed by Booth, et al. To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. *In re Henze*, 85 USPQ 261 (1950). The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologues of the compounds taught in the reference with the expectation of obtaining compounds which could be used in perfume compositions. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Furthermore, the typical practicing chemist (one of ordinary skill in the art) would know that wherein there is a known process in the art (see specification, page 2, lines 6-16), the mere use of different starting materials in a conventional process to produce the product one would expect therefrom does not render the process unobvious. *In re Surrey, et al.* (CCPA 1963) 319 F2d 283, 138 USPQ 67 and *In re Kanter*, (CCPA 1968) 399 F2d 249, 158 USPQ 1069. No more than routine skill is involved in adjusting reaction parameters including starting material concentrations, changes in temperature, or other process conditions of a known process, in order to achieve the result taught in the prior art. *Ex parte Rasmussen* (POBA 1959) 123 USPQ 498 and *In re Aller, et al.* (CCPA 1976) 531 F2d 1048, 189 USPQ 233. Additionally,

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modifications, with respect to selection of variables within the broad teaching of the prior art, are not patentable if the achieved results vary merely in degree from that obtained in the prior art. *In re Aller, et al.* (CCPA 1955) 220 F2d 454, 105 USPQ 233. Also, one of ordinary skill in the art is provided direction to further modify the process as disclosed in the Booth reference wherein the reference specifically states that "No attempt has been made to optimize the yields of compounds (7b) and (8) [compound 8 is recited in this office action in both the 102(b) and 103(a) rejections], and their low recovery problem...." (see page 1522, left-hand column, about 1/3 down the paragraph), in an attempt to optimize said conditions.

During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. *In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023. However, the examiner cannot read limitations from the specification into the claims.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer C. Murphy, whose telephone number is (703) 305-0159. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Joseph.McKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet

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Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1234.

Jennifer C. Murphy
November 18, 2002

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